

SUPPORTING STATEMENT

Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)

A. JUSTIFICATION

1. Necessity of the Information Collection

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) requires FDA to collect a user fee from each person who submits certain medical device applications for FDA review. MDUFMA user fees for FY 2003 ranged from \$2,187 to \$154,000, depending on the type of application (FDA will publish updated fees for FY 2004 in early August 2003). See § 738(a)(1) and § 738(c)(5) of the Federal Food, Drug, and Cosmetic Act (all further citations in this notice are to that act). A “small business” is eligible for reduced or waived fees; small business fees for FY 2003 range from \$2,187 to \$58,520. § 738(d)(2)(B) and § 738(e)(2)(B) If an applicant does not provide information to FDA demonstrating to FDA’s satisfaction that the applicant is a small business, the applicant must pay the standard (full) fee for any application it submits.

The FY 2004 MDUFMA Small Business Qualification Certification (hereafter referred to as Form FDA 3602) will permit an applicant to certify that it qualifies as a “small business” within the meaning of the Medical Device User Fee and Modernization Act (MDUFMA), will help the applicant organize the information FDA needs to verify each certification, and will collect contact information to facilitate rapid resolution of any questions FDA may have concerning information the applicant has provided. FDA is requesting this emergency processing under the PRA of 1995 to implement § 738(d)(2)(B) and § 738(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act); these provisions were added to the act by section 102 of MDUFMA.

Sections 738(d)(2)(A) and 738(e)(2)(A) define a “small business” as an entity that reported \$30 million or less of gross receipts or sales in its most recent Federal income tax return, including such returns of its affiliates, partners, and parent firms.

2. How, by Whom, and for What Purpose Information is Used

FDA is the sole user of the information collected through a Form FDA 3602. The form itself will also serve to help entities understand the statutory requirements they must meet to qualify as a “small business.”

FDA will use the information submitted on Form FDA 3602 to decide whether the entity meets the requirements of § 738(d)(2)(A) and § 738(e)(2)(A). FDA’s review of each Form FDA 3602 will ensure that the entity has identified all of its affiliates, partners, or parent firms, and that the total gross receipts and sales of the entity (including all affiliates, partners, or parent firms) is no more than \$ 30

million. If the entity qualifies as a “small business,” FDA will inform the entity that it is eligible for reduced or waived fees for all medical device applications it submits to FDA during FY 2004.

3. Use of Improved Information Technology

Because § 738(d)(2)(B) and § 738(e)(2)(B) specifically require an entity to submit “a copy of its most recent Federal income tax return . . . and a copy of such returns of its affiliates, partners, and parent firms” as evidence that it qualifies as a MDUFMA small business, FDA is not providing for the use of improved information technology for FY 2004.

4. Identification of Duplication and Similar Information Already Available

Form FDA 3602 does not duplicate any other information collection.

5. Small Business

Form FDA 3602 collects the minimum information FDA requires to efficiently and quickly determine whether an entity is a small business. Because § 738(d)(2)(B) and § 738(e)(2)(B) specify the evidence that an entity must submit to qualify for small business fees or waivers, there is no way to reduce the information collection.

Staff from FDA and the Small Business Administration (SBA) met on May 14, 2003, to discuss a possible role for SBA in determining whether a business entity qualifies as a “small business” within the meaning of MDUFMA. The statutory criteria employed by MDUFMA (“gross receipts or sales”) is different from the criteria normally employed by SBA in classifying an entity as a small business (SBA usually looks to the *number of employees* at the entity). Although SBA believed the process used by FDA is a reasonable approach, and they had no objection to using FDA’s criteria and process, SBA does not have sufficient resources to review the 3,000 Small Business Qualification Certifications expected by FDA during FY 2004. Consequently, FDA will retain this workload for the present.

6. Consequences if Data Were Collected Less Frequently

Data is collected only once for FY 2004.

7. Special Circumstances

MDUFMA was enacted October 26, 2002. Applicants will be required to pay user fees as soon as Congress passes an authorizing appropriation. An applicant must pay the standard (full) fee unless FDA decides the applicant is a “small business” within the meaning of MDUFMA. FDA cannot make this determination for FY 2004 unless we have the information collected on and with the Form FDA 3602.

8. Outside Consultation

FDA consulted with an association that represents small medical device manufacturers, and we used information from previous discussions with small manufacturers and industry to estimate the number of entities that will choose to submit a Form FDA 3602.

In the Federal Register of July 18, 2003 (68 Fr 42742), FDA requested comments from the public. No comments were received.

9. Gifts

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality

Information that is trade secret or confidential commercial information is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Sensitive Information

This information collection does not involve any questions of a sensitive nature.

12. Respondent Hour Burden and Annualized Burden Cost Estimates

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

Requirement	Number of Respondents	Total Annual Responses	Hours per Response	Total Hours	Total Operating, Capital, or Maintenance Costs
Form FDA 3602	3,000	3,000	1	3,000	0

This information collection does not involve any recordkeeping requirements.

This burden includes time required to collect the required information, to copy each required Federal income tax return, and to complete the form. FDA believes most entities that submit a Form FDA 3602 will not have any affiliates, partners, or parent firms; FDA believes very few will have more than three or four affiliates, partners, or parent firms.

Estimated Annualized Cost for Burden Hours

The total cost burden (1 hour, for a total cost of \$70) is attributable to completion and submission of the Form FDA 3602 and copying and including a copy of each required Federal income tax return.

13. Annual Cost Burden to Respondent

There are no operating, maintenance, or other continuing costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA will review each Form FDA 3602 and each accompanying Federal income tax return to confirm the accuracy of information provided for an entity and to ensure that the entity qualifies as a "small business" within the meaning of MDUFMA. As part of its review, FDA will review commercial data bases to determine whether the entity has any affiliates, partners, or parent firms that it did not identify on the Form FDA 3602. FDA believes it will have to expend approximately 1 hour of effort on each Form FDA 3602. We doubled the hourly rate for a GS-14 (\$35) to account for overhead (total, \$70 per hour). With 3,000 submissions to be reviewed, FDA estimates that the total cost to the Federal government will be \$210,000.

15. Changes or Adjustments in Burden

Many more applicants will have an interest in qualifying as MDUFMA "small business" beginning with FY 2004. During FY 2003, there was no reduced small business fee for 510(k)s -- everyone, large and small alike, paid the same fee. Beginning with FY 2004, a reduced 510(k) fee will be available to applicant who have qualified as a small business (a small business will get a 20% discount, and will pay \$2,827 instead of the standard (full) fee of \$3,533).

16. Statistical Analysis, Publication Plans, and Schedule

Not applicable.

17. Approval Not to Display Expiration Date

FDA will display an October 1, 2004 expiration date on the Form FDA 3602, as it will not be used after September 30, 2004.

18. Exceptions to the Certification Statement Identified in Item 19

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

FDA does not plan to publish the information collected under the provisions of this proposed regulation for statistical use. This collection of information does not employ statistical methods.